

## Frequently Asked Questions on the Emergency Use Authorization for Veklury (remdesivir) for Hospitalized COVID-19 Patients

### **Q. What is an Emergency Use Authorization?**

A: Under section 564 of the Federal Food, Drug & Cosmetic Act, the FDA may, pursuant to a determination and declaration by the HHS Secretary, authorize an unapproved product or unapproved uses of an approved product for emergency use. In issuing an EUA, the FDA must determine, among other things, that the product may be effective in diagnosing, treating, or preventing a serious or life-threatening disease or condition caused by a chemical, biological, radiological, or nuclear agent; that the known and potential benefits outweigh the known and potential risks for the product; and that there are no adequate, approved, and available alternatives. Emergency use authorization is NOT the same as FDA approval or licensure.

### **Q. What does this EUA allow?**

A. The [EUA](#) authorizes Veklury (remdesivir), manufactured by Gilead, for emergency use by healthcare providers to treat suspected or laboratory-confirmed coronavirus disease 2019 (COVID-19) in all hospitalized adult and pediatric patients.

### **Q. How is the revised EUA for Veklury (remdesivir) different than the EUA initially granted on May 1, 2020?**

On May 1, 2020, FDA granted Gilead's EUA request authorizing Veklury (remdesivir) for emergency use by licensed health care providers to treat suspected or laboratory-confirmed COVID-19 in hospitalized adult and pediatric patients with severe disease. When initially granted, the EUA limited the authorization of Veklury (remdesivir) to hospitalized adult and pediatric patients with severe disease, which was defined as patients with low blood oxygen levels or needing oxygen therapy or more intensive breathing support such as a mechanical ventilator.

On August 28, 2020, based on the totality of scientific information available, including data that have become available since the May 1 original issuance of the EUA, FDA revised the emergency use authorization (EUA) for Veklury (remdesivir) to broaden the scope of its authorized uses. Under the revised [EUA](#), Veklury (remdesivir) is authorized for emergency use by healthcare providers for the treatment of suspected or laboratory-confirmed COVID-19 in all hospitalized adult and pediatric patients, irrespective of their severity of disease.

### **Q. Is Veklury (remdesivir) approved by the FDA to treat COVID-19?**

A. No. Veklury (remdesivir) is an investigational antiviral drug. It is not currently FDA-approved to treat or prevent any diseases, including COVID-19.

In August 2020, Gilead announced publicly the submission of their New Drug Application (NDA) for Veklury (remdesivir) for the treatment of COVID-19. See <https://www.gilead.com/news-and-press/press-room/press-releases/2020/8/gilead-submits-new-drug-application-to-us-food-and-drug-administration-for-veklury-remdesivir-for-the-treatment-of-covid19>

### **Q. Are there data showing Veklury (remdesivir) might benefit patients with COVID-19?**

#### **A. In Vitro Data:**

In vitro (laboratory) testing of Veklury (remdesivir) demonstrated it is active against SARS-CoV-2 (the virus causing COVID-19).

### Data from Phase 3 Clinical Trials:

#### NIAID ACTT-1 Trial

Preliminary results from a Phase 3, placebo-controlled clinical trial of Veklury (remdesivir) by the National Institute for Allergy and Infectious Diseases suggested that patients taking Veklury (remdesivir) experienced faster time to recovery as compared to patients taking a placebo. This trial included a sizeable proportion of patients who were receiving mechanical ventilation or extracorporeal membrane oxygenation (ECMO) at baseline. Based on these findings, the Fact Sheet for Health Care Providers details a 10-day treatment course for patients receiving mechanical ventilation or ECMO.

#### Gilead GS-US-540-5773 Trial

Preliminary results from a different Phase 3 trial evaluating 5-day and 10-day dosing durations of Veklury (remdesivir) in hospitalized patients with severe COVID-19 disease reported that patients receiving a 5-day treatment course demonstrated similar clinical status at Day 14 as those taking a 10-day treatment course; however, importantly, very few patients in this trial were receiving mechanical ventilation or ECMO at baseline. Therefore, based on these findings, the Fact Sheet for Health Care Providers details a 5-day treatment course for patients who are not receiving mechanical ventilation or ECMO. Patients who receive a 5-day treatment course but do not demonstrate clinical improvement are eligible to continue to receive Veklury (remdesivir) for an additional 5 days.

#### Gilead GS-US-540-5774 Trial

Data from a randomized clinical trial of hospitalized patients with confirmed COVID-19 and radiological evidence of pneumonia without an oxygen requirement during screening compared treatment with Veklury (remdesivir) for 5 days and 10 days with standard of care. The odds of improvement in clinical status were higher in the 5-day Veklury (remdesivir) group at Day 11 when compared to those receiving the standard of care. The odds of improvement in clinical status with the 10-day treatment groups when compared to patients receiving the standard of care were not statistically significant.

The safety and efficacy of Veklury (remdesivir) for the treatment of COVID-19 are being evaluated in multiple ongoing clinical trials.

Because Veklury (remdesivir) may help hospitalized patients, FDA is allowing this drug to be provided to hospitalized patients, irrespective of disease severity, under an expansion of the [EUA](#) issued on August 28, 2020. Under the EUA, [health care providers](#) and [patients](#) are provided with information about the risks of Veklury (remdesivir). However, a review of final data from clinical trials included in the New Drug Application (NDA) is necessary for us to determine whether the drug is safe and effective in treating COVID-19.

#### **Q. Are there clinical trials underway evaluating Veklury (remdesivir) for COVID-19?**

A. Yes. [Clinical trials](#) remain ongoing to study Veklury (remdesivir) for investigational uses.

#### **Q. Are there side effects of Veklury (remdesivir)?**

A. Possible side effects of Veklury (remdesivir) are:

- Hypersensitivity reactions, including infusion-related and anaphylactic reactions. Hypersensitivity reactions, including infusion-related and anaphylactic reactions, have been seen during a Veklury (remdesivir) infusion or around the time Veklury (remdesivir) was given. Signs and symptoms may

include: low blood pressure, high heart rate, low heart rate, shortness of breath, wheezing, swelling (e.g. lips, around the eyes, under the skin), rash, nausea, vomiting, sweating, and shivering.

- Increases in levels of liver enzymes, seen in abnormal liver blood tests. Increases in levels of liver enzymes have been seen in people who have received Veklury (remdesivir), which may be a sign of inflammation or damage to cells in the liver.

These are not all the possible side effects of Veklury (remdesivir). Veklury (remdesivir) is still being studied so it is possible that all of the risks are not known at this time.

**Q. How can Veklury (remdesivir) be obtained for use under the EUA?**

A. HHS' Office of the Assistant Secretary for Preparedness and Response (ASPR) [announced](#) the allocation plan for Veklury (remdesivir) in May 2020. On June 29, 2020, HHS [announced](#) an agreement between HHS and Gilead to secure large supplies of Veklury (remdesivir) through September 2020. These supplies will be allocated in the same way that Gilead's donation of approximately 120,000 treatment courses of Veklury (remdesivir) were allocated: HHS allocates product to state and territorial health departments based on COVID-19 hospital burden, and health departments allocate it to hospitals. Healthcare providers interested in administering Veklury (remdesivir) in accordance with the authorized use under the EUA should contact their state health department. More information about allocation of Veklury (remdesivir) can be found [here](#).

Outside of the EUA, Veklury (remdesivir) remains available through [Emergency investigational new drug applications \(EINDs\)](#) for pregnant women and children if they cannot gain access to Veklury (remdesivir) via the EUA.

**Q. Does the EUA permit Veklury (remdesivir) to be used outside the hospital (non-hospitalized patients)?**

A. No. Use of Veklury (remdesivir) in a non-hospital setting is outside the scope of the Emergency Use Authorization.

**Q. Is there a requirement for providers to report side effects as part of the EUA?**

A. Yes. As part of the EUA, FDA is requiring health care providers who prescribe Veklury (remdesivir) to report all medication errors and serious adverse events considered to be potentially related to Veklury (remdesivir) through FDA's [MedWatch Adverse Event Reporting](#) program. Providers can complete and submit the report [online](#); or download and complete the [form](#), then submit it via fax at 1-800-FDA-0178. This requirement is outlined in the EUA's health care provider [fact sheet](#). FDA MedWatch forms should also be provided to Gilead.

**Q. Do patient outcomes need to be reported under the EUA?**

A. No, reporting of patient outcomes is not required under the EUA. However, reporting of all medication errors and adverse events considered to be potentially related to Veklury (remdesivir) occurring during Veklury (remdesivir) treatment is required.

**Q. Does the EUA authorize Veklury (remdesivir) to be used to prevent COVID-19?**

A. No. Veklury (remdesivir) is authorized for emergency use by healthcare providers to *treat* suspected or laboratory-confirmed coronavirus disease 2019 (COVID-19) in hospitalized adult and pediatric patients. Use of Veklury (remdesivir) for the prevention of COVID-19 is not authorized and outside the scope of the Emergency Use Authorization.

**Q. How does this EUA add to/differ from the existing Expanded Access approval?**

A. An EUA is a temporary measure, pursuant to a Secretary of Health and Human Services declaration, in which the FDA Commissioner may authorize unapproved medical products or unapproved uses of approved medical products for use in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by chemical, biological, radiological or nuclear (CBRN) threat agents. In issuing an EUA, the FDA must determine, among other things, that the product may be effective in diagnosing, treating, or preventing a serious or life-threatening disease or condition caused by the CBRN agent; that the known and potential benefits outweigh the known and potential risks for the product; and that there are no adequate, approved, and available alternatives.

On May 1, 2020, FDA granted Gilead's EUA request authorizing Veklury (remdesivir) for emergency use by licensed health care providers to treat suspected or laboratory-confirmed COVID-19 in adult and pediatric patients hospitalized with severe COVID-19. On August 28, 2020, FDA revised the EUA authorizing Veklury (remdesivir) for emergency use by healthcare providers to treat all hospitalized adult and pediatric patients with suspected or laboratory-confirmed COVID-19. FDA's EUA for Veklury (remdesivir) is subject to the conditions as detailed in the [letter of authorization](#).

While EUAs may only be issued while the Secretary of Health and Human Services declaration justifying emergency use is in effect, requests for expanded access to an investigational drug may be submitted to FDA and considered at any time. Expanded access is a potential pathway for a patient with a serious or immediately life-threatening disease or condition to gain access to an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available. Expanded access requires submission of an expanded access protocol to an existing investigational new drug application (IND) or a new expanded access IND, and is subject to certain IND requirements, such as IND safety reporting and informed consent.

For Veklury (remdesivir), the following mechanism may be available for expanded access:

- Treatment under emergency investigational new drug applications (EINDs) for pregnant women and children less than 18 years of age with confirmed COVID-19 or severe manifestations of disease if they cannot gain access to Veklury (remdesivir) via the EUA.

For more information about expanded access to Veklury (remdesivir), please contact Gilead or refer to the following webpage: [Emergency Access to Veklury \(remdesivir\) Outside of Clinical Trials](#).

**Q. Why has a warning about drug interactions between hydroxychloroquine sulfate/chloroquine phosphate and Veklury (remdesivir) been added to the healthcare provider Fact Sheet?**

A. Laboratory testing was conducted that raised serious concerns about a risk of reduced antiviral activity for Veklury (remdesivir) when Veklury (remdesivir) is co-administered with chloroquine phosphate (CQ) or hydroxychloroquine sulfate (HCQ). This means there is the potential for Veklury (remdesivir) to not work as well to treat COVID-19 when it is taken with CQ/HCQ. Although further testing needs to be done, FDA has determined that the data are sufficient to warn health care providers, and FDA recommends against administering the drugs together.

**Q. What if I take hydroxychloroquine sulfate for a chronic condition? Does this mean I should not take Veklury (remdesivir)?**

A. There is the potential for Veklury (remdesivir) to not work as well to treat COVID-19 when it is taken with hydroxychloroquine sulfate (HCQ) or chloroquine phosphate (CQ). FDA recommends against taking the drugs together. If you are taking HCQ or CQ, discuss your options and specific situation with your health care provider.

**Q. What is FDA doing to facilitate the development and expedite the review of Veklury (remdesivir)?**

A. On March 26, 2020, FDA granted Fast Track designation to Gilead for Veklury (remdesivir), which among other things, maximizes the opportunities for Gilead to engage with the Agency on its development of remdesivir for the treatment of COVID-19.

Based on this designation, on April 6, 2020, FDA granted Gilead's request and accepted its proposal to allow for a rolling review of its development program for Veklury (remdesivir). Under this process, Gilead could submit and FDA reviewed sections of Gilead's New Drug Application (NDA) for Veklury (remdesivir) as they arrived. Under traditional processes, FDA's review of an NDA does not begin until the sponsor has submitted the entire application to the Agency.

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**Q. Can health care providers share the patient/caregiver Fact Sheet electronically?**

A. The letter of authorization for Veklury (remdesivir) requires that Fact Sheets be made available to healthcare providers and to patients/caregivers, "through appropriate means." Electronic delivery of the Fact Sheet is an appropriate means, for example, when the patient requests it electronically, the Fact Sheet is delivered as a PDF (not a URL), and the patient is able to obtain access to the electronic version prior to receiving the medicine. Additionally, health care providers should confirm receipt of the fact sheet with the patient. Paper copies must be available for patients who request them.